



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,695	03/27/98	BILLING-MEDEL	P 6066.US.PI

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HM12/0604

EXAMINER

BURKE, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/049,695

Applicant(s)

Billing-Medel

Examiner
Julie E. Burke, (Reeves), Ph.D.

Group Art Unit
1642



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire zero month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-18 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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~~Oath/Declaration~~

~~Signed~~
Signed Oath filed 6/24/99
as Page #5.

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it was not executed in accordance with either 37 CFR 1.66 or 1.68.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, ¹¹~~12~~, 15, 17-18 drawn to CS197 polynucleotide host cells and methods ^{9b} _{26m⁹⁹} of expressing, classified in class 536, subclass 23.1, for example.
- II. Claims 7-9, 16 drawn to CS197 polypeptide, classified in class 530, subclass 350.
- III. Claims 10, drawn to an antibody specific for a CS197 polypeptide, classified in class 530, subclass 387.1+.
- IV. Claim 13, drawn to a method of producing antibodies by administering an isolated immunogenic polypeptide, classified in class 424, subclass 174.1.
- V. Claim 14, drawn to a method of producing antibodies by administering an plasmid comprising a polynucleotide sequence which encodes CS197 polypeptide, classified in class 514, subclass 44.

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3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects. The polynucleotides of Invention I can be used as hybridization probes for screening libraries or tissues for CS197 gene, a technique which cannot be achieved with the polypeptide of invention II. Invention II can be used to raise anti-CS197 antibodies, a technique which cannot be performed with the polynucleotides of Invention II. The Antibodies of Group III can be used to screen libraries, a technique which cannot be practiced with the protein or polynucleotides of groups I or II. Thus Inventions I, II and III are patentably distinct.

4. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects. The method of treatment by vaccinating with a protein differs from the method of vaccinating using a plasmid because these methods use different products (polypeptides vs polynucleotides) and because these methods have different modes of operation (classical vaccination methods vs gene therapy method). Thus Inventions IV and V are patentably distinct.

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5. Inventions (IV and V) and Inventions (I, II and III) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the products of Inventions I, II or III can be used for the practice of other inventions, such as immunopurification or diagnostics, besides those methods of making an antibody as recited in the Groups IV and V.. Thus Inventions (IV and V) and Inventions (I, II and III) are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. A telephone call was made to Cheryl Becker on 26 May 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, née Reeves, Ph.D, whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,



Julie E. Burke, née Reeves, Ph.D.

Patent Examiner

(703) 308-7553

JULIE BURKE
PRIMARY EXAMINER